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SYMPOSIUM: CLINICAL RISK AND JUDICIAL REASONING

Medical Malpractice

The Experience in Italy

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Abstract At the present time, legal actions against physicians in Italy number about 15,000 per year, and hospitals spend over €10 billion (~US$15.5 billion) to compensate patients injured from therapeutic and diagnostic errors. In a survey summary issued by the Italian Court for the Rights of the Patient, between 1996 and 2000 orthopaedic surgery was the highest-ranked specialty for the number of complaints alleging medical malpractice. Today among European countries, Italy has the highest number of physicians subject to criminal proceedings related to medical malpractice, a fact that is profoundly changing physicians' approach to medical practice. The national health system has paid increasingly higher insurance premiums and is having difficulty finding insurance companies willing to bear the risk of monetary claims alleging medical malpractice. Healthcare costs will likely worsen as Italian physicians increasingly practice defensive medicine, thereby overutilizing resources with the goal of documenting diligence, prudence, and skill as defenses against potential litigation, rather than aimed at any patient benefit. To reduce the practice of defensive medicine and healthcare costs, a possible solution could be the introduction of an extrajudicial litigation resolution, as in other civil law countries, and a reform of the Italian judicial system on matters of medical malpractice litigation.

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Introduction

In Italy, the historical interpretation of medical negligence was founded in establishing gross negligence on the part of the treating doctor; this philosophy limited the number and scope of malpractice cases filed against physicians. One study in the late 1980s reported a 50% increase in the number of medical malpractice cases filed in 1986 compared to 1985, and another 90% increase in 1987 [55]. Since then, the professional liability landscape has changed in Italian healthcare, resulting in a major expansion of case studies.

In addition to increased numbers of claims filed against doctors, the size of payments to allegedly injured patients has increased dramatically, moving from mere token amounts paid to victims of medical malpractice to the increasingly greater sums of money paid since the late 1980s. In part, this trend may reflect technological advances in healthcare and how judges view these advances. While in the past, the physician had an obligation to use all available means to achieve the result without being legally obliged to actually achieve the result, now the physician is more frequently called to answer for any result falling short of patient expectations [43].

In Italy today, more than 15,000 medical liability actions are filed per year against doctors, and hospitals (through their insurance companies) must spend over €10 billion (~US$15.5 billion) annually to compensate for therapeutic and diagnostic errors [21]. Between 1996 and 2000, orthopaedics and traumatology were responsible for the highest number of cases filed relating to alleged malpractice, followed by obstetrics/gynecology. Estimates suggest a physician practicing in Italy for 20 years has an 80% chance of being named as a defendant in a medical malpractice suit, with an 80% chance of being exonerated

for charges of negligence, imprudence, or unskillfulness [18]. Fattorini et al. [18] reviewed 123 complaints filed against specialists in orthopaedics and traumatology in five Italian regions, namely, Campania, Emilia-Romagna, Lombardy, Puglia, and Sicily. More than 72% of these cases were related to trauma care, usually concerning the outcome of long-bone fractures of the limbs, and usually in association with muscle and nerve lesions. In elective orthopaedic cases, most allegations of negligence were related to the outcomes of surgery on degenerative spines and arthroplasty of the knee and hip joints. These results are similar to trends observed in the United States where most medical negligence cases in orthopaedic surgery are related to long-bone fracture care and spinal surgery [76].

Little attention has been paid to Italian medical liability and medical malpractice litigation in international medical journals. The main cause is probably the complexity of the approach of the Italian medicolegal system (of continental Europe derivation), which is completely different from the medicolegal systems of Anglo-Saxon derivation, thus the Italian medicolegal literature is mainly published in non-medical journals, spread in unpublished theses, legal monographs, or chapters of textbooks for students in law universities.

The aim of this study is to review the state of medical liability in Italy and to compare it with international experiences. In the first part of this review, the Italian legal system and the body of laws governing medical liability in Italy will be briefly explained, stressing the essential differences of the laws and the judicial system from those of Anglo-Saxon derivation. Then, the key role of informed consent in regulating the physician-patient relationship and the consequences on physician liability will be shown. In addition, the Italian malpractice insurance system in a healthcare with a predominant prevalence of public healthcare will be described, in order to better define the environment in which an Italian physician must work. Finally, a comparison with other experiences will be made to identify possible solutions to the large number of alleged malpractice litigations filed against Italian physicians, raising the costs of the national healthcare system and of insurance policies.

The Italian Legal System

Italy is a civil law country. Civil law (or continental law) is based on Roman law, especially the Corpus iuris Civilis or Corpus iuris Iustinianeum (of Roman Emperor Justinian). Civil law as a legal system is often compared with common law. Common law legal systems are in use in those nations that trace their legal heritage to Britain, including the United Kingdom, United States (except Louisiana), and Canada (except Quebec), and other former colonies of the British Empire. The main difference between the two systems is that civil law starts with abstract rules, which judges must then apply to the various cases, whereas common law draws abstract rules from specific cases. This difference explains why the civil law is usually defined "professors' law" and the common law "lawyers' law" [8]. The differences between the two legal systems also influence the medical liability laws, for example in the Italian civil law system the breach of duty of care does not exist, while negligent personal injuries (lesioni personali colpose) that are not included in common law systems are prosecuted [9]. By contrast in the United States, a successful tort claim requires four legal elements: (1) duty of care; (2) breach of duty; (3) injury; (4) proximate cause.

In Italy, the legal administration of a case of medical malpractice (both for criminal and civil proceedings) is settled in the first grade by a court of first instance (Tribunale); in the second grade by the Court of Appeal (Corte d'Appello); and in third grade by the Court of Cassation (Corte di Cassazione), as a court of legitimacy.

The Court of Cassation is the court of last resort for both the civil and the criminal jurisdiction, and has the power to correct a lower instance court's interpretation or application of the law. It is arranged in divisions (both criminal and civil, but also administrative and military); when two or more divisions disagree on a legal interpretation, the case is submitted to the United Divisions (Sezioni Unite).

For malpractice cases, a physician is both liable to prosecution (in a criminal court) and civil action (in a civil court). If a medical procedure is vitiated by a serious error in conduct, which causes injury to the patient, and there is a chain of causality between medical error and the damage suffered by the patient, the doctor may be held criminally liable for negligent personal injuries (lesioni personali colpose) [72]. Indeed, in Italian law, a crime for negligent personal injury is criminally liable to private prosecution (querela) by the person offended (in this case the patient). In the Italian penal code, the negligent injury is described as "an event that, even if it happened against the intention, occurred due to negligence, imprudence, unskillfulness or failure to comply with laws, regulations, orders and disciplines" (art. 43, Italian Penal Code).

A physician in a case of negligent conduct is also civilly liable. The civil liability is the legal consequence of any illicit professional conduct. It is identified if there is a chain of causation between the illicit professional conduct and the event. The typical remedy of legal proceeding for civil liability is compensation of the damage.

The diligence of the physician is "scrupulous attention and adequate medical preparation" [33], and he is liable for negligence or imprudence, without distinguishing between slight or gross fault (colpa grave o lieve). When the

negligence, imprudence, or unskillfulness is a consequence of complex or extraordinary situations, the physician is liable for gross fault in every case and for slight fault in cases of negligence or imprudence (but not for unskillfulness) [34, 40, 41]. This distinction of gross or slight fault does not apply in common law systems [10].

The fault is gross (colpa grave) if the minimum rules of skill are violated, and it consists of the nonapplication of those skills that fall within the minimum knowledge required for a doctor [32]. The fault is slight (colpa lieve) when the omission of care (for negligence or imprudence), due to insufficient preparation for a case, leads to damage to the patient (both in the execution of surgical treatment or medical therapy); for example, in the case of a patient lacking information about the likely debilitating outcome of a surgery [29].

Negligence (negligenza) consists of lack of care, and implies passive behavior that is reflected in the omission of necessary precautions. For example, when the surgeon leaves clips, instruments, or gauze sponges in the surgical wound, operates the healthy limb, does not control the date of expiry of drugs, or fails to provide necessary preliminary investigations.

Imprudence (imprudenza) consists of a given medical action without taking all the precautions that common experience suggests is necessary, and implies active behavior that translates into a reckless behavior; that is behavior unconscious of the possible dangers verifiable with a reasonable probability. Imprudence occurs when the surgeon, for example, performs complex and delicate surgery despite knowing that he is not in perfect physical condition, or without having the appropriate equipment, or performs a particularly challenging surgery without having the capacity to do so.

Unskillfulness (imperizia) consists of a poor attitude in those activities which require special technical knowledge and implies a deficiency of culture, practice, intuition and capacity of observation [60]. For example, when the doctor falls short of the minimum skills and technical expertise in the use of instruments, which he should be sure to use correctly; or in the misdiagnosis of an easy case.

In summary, the Italian physician has, in the course of his activities, civil and criminal liability. This means that he will respond, in every case of alleged negligence or imprudence in civil courts for the damage possibly caused to the patient, and probably in criminal courts for negligent personal injuries (lesioni personali colpose).

Medical Liability Law in Italy

In Italy there is no specific law code for the physician-patient relationship, so the rules of the relationship mainly evolve through the Court of Cassation jurisprudence. The physician, as public or private hospital employee or independent practitioner, has a contractual obligation towards the patient as far as liability is concerned. Thus, tort law liability rules are not applicable in cases of medical malpractice: rather, principles of contract law formally regulate the position of doctors before patients [28, 38]. Recently, the judges of the Court of Cassation have reaffirmed that both the responsibility of the Hospital and the physician are contractual liability, in the first case on the basis that "the acceptance of the patient in the hospital for admission or for a clinical control, involves the conclusion of a contract," and in the second because it establishes between patient and physician a "social contact" with a contractual nature [28]. This court law applies also to private hospitals and to physicians who practice out of the national healthcare system without any difference [35].

The consequences are relevant: First, the burden of proof is on the defendant (physician or hospital), second, all laws applicable to professional diligence are pertinent, and third, the statute of limitations (the statute that sets forth the maximum period of time, after certain events, that legal proceedings based on those events may be initiated) is that peculiar to contracts and set at 10 years rather than the 5 for compensation claims not originating from a contract (from tort). This is five times more than the 2 years established by U.S. legislation [53]. In other words, in Italy a physician could be called to answer for malpractice 10 years after a medical procedure, and would have to prove his innocence.

The Court of Cassation has articulated a "good father of a family" standard for physician conduct, holding that in addition to intentional or grossly negligent conduct, a physician can also be liable for violating the ordinary standard of care relating to professional preparation, scrupulous attention, and adequate training [30]. This standard is comparable to the United States, where physicians have a legal duty to adhere to a reasonably prudent standard of care [76].

Unlike the United States, the sort of burden of proof in medical negligence cases in Italy depends on the nature of the medical procedure. If the medical procedure (nonoperative or operative treatment) is routine, commonly performed, and straightforward, then the physician faced with an adverse outcome is burdened with showing that such an outcome was not the result of negligence, imprudence, or lack of skill. Conversely, if the medical procedure is complex or unusual, the patient is burdened with showing that the procedure was unnecessary, or that physician malice or serious negligence contributed to a poor outcome.

The Court of Cassation settles the double nature of the medical obligation: an obligation of means for especially

complex procedures and obligation of outcome for routine procedures. A procedure may be classified as especially complex when "within medical science, different and incompatible diagnostic and therapeutic methods or surgical techniques are available and discussed" [44]. The res ipsa loquitur doctrine (a legal term from the Latin meaning "the thing speaks for itself" which signifies that the proof of the case is self-evident) is usually applied to routine procedures.

With regard to omissive conduct (eg, cases of missed diagnosis), the chain of causality between the omission and the event is configurable, hypothetically, only if the necessary action had been taken, the event would not have taken place with a high degree of rational credibility, or it would have taken place substantially later, or with less detrimental intensity [27].

The eligibility of a claim for omissive professional negligence cannot exist unless it is demonstrated by the plaintiffs' attorneys a direct and unequivocal detrimental capacity of the physician omission [19, 58].

Informed Consent in Italy

Article 32 of the Italian Constitution stipulates that "no one can be compelled to undergo any certain medical treatment except as a specific provision of the law," in line with the fundamental principle of inviolability of personal liberty (Article 13, Italian Constitution, December 27, 1947). The medical treatment is mandatory, for example, when a person is considered under conditions of high psychic discomfort [45], or in emergency situations when the patient is unable to express his consent, regardless of the will of any relatives [16]. In all the other cases, the only way to achieve full respect for the individual in need of care is to establish voluntary consent before any medical procedure; this implies an information exchange about the procedure and its possible complications. This principle, also embodied in the informed consent doctrines of other countries, embodies patient autonomy, and the absolute right to accept or reject any treatment after being fully informed. Relevant Italian Court of Cassation citations read as follows:

"This consensus is one of the elements of the contract between the patient and the professional (Article 1325, Italian Civil Code) concerning the professional provision, so the information requirement is also due to a behaviour in good faith which is required in the conduct of negotiations and in the formation of the contract (art. 1337, Italian Civil Code)" [31]. If the information is missing, in whole or in part, there will be a responsibility of guilty omission [42].

The jurisprudence and doctrine reflected above have focused their attention on the obligation to inform the patient about the nature and risks related to the treatment, in order to obtain informed consent for treatment. While these doctrines may appear similar to those used to develop informed consent guidelines in the United States, their objectives, applications, and influence medical litigation have evolved differently in Italy [54].

Physician Insurance in Italy

The National Heath Care system in Italy insures medical staff employees, providing compensation to victims of alleged malpractice, including reasonable court fees. Thus, the public healthcare administration has the power to insure its employees against the risk of civil liability, but the administration itself can also decide not to do so. Compensation to patients derives from Article 28 of the Italian Constitution that specifies, "…officials and employees of the State are directly responsible of acts in violation of rights, according to the criminal, civil and administrative laws. In such cases, the liability extends to the State and public bodies" [26]. Thus, unlawful acts committed by a physician-employee of the Hospital Authority or the National Health System lead to both personal liability on the part of the physician and liability on the part of the public body.

These laws have had an impact on the budget of public hospitals, which have had to pay out increasing insurance premiums and find insurance companies willing to issue protection. Furthermore, the insurance policies require an amount to be borne by the insured (usually 10% of the compensation). In the case of intentional or gross negligence, both the insurance company and the hospital administration can also file claims against the negligent physician, thus making the purchase of individual coverage mandatory for Italian physicians, even if they are employed in the public health system. All forms of professional liability insurance for physicians in Italy are issued on a claims-made basis, thereby making it necessary for physicians to purchase coverage extending into the future for as long as a claim could reasonably arise.

Discussion

The 2005 budget for healthcare in Italy was some 8.9% of GDP; which was lower than in Germany (10.7%), France (11.1%), Switzerland (11.6%), and the United States (15.3%) [65]. According to the World Health Organization, Italy is second in the world after France for quality and accessibility of health services to a population that has among the highest indices of old age in the world [79]. On the other hand, worldwide, Italy also has the absolute

highest number of physicians subject to criminal proceedings originating from a medical malpractice claim (more than 10,000 new criminal proceedings per year) in civil law countries [61]. Physicians are criminally liable in most civil law countries (ie, Spain, France, and Germany) [3, 13, 68], but in Italy most claims are pursued through the criminal courts because all the expense of evidence gathering and prosecution are supported by the State and not by the claimant. Civil proceedings are usually longstanding, and the criminal proceeding does not preclude a subsequent civil claim. Furthermore, with a successful criminal proceeding in Italy it is possible to achieve both compensation in terms of monetary payments and criminal penalties, while this does not apply in common law systems [11].

Generally, when a claim is pursued through a criminal court, the prosecutor bases his inquiry on documents and surreptitious examination of the patient and orders the sequester of the clinical files of the patient, leaving the physician without access to his own records [47]. In part this reflects a legal system that has given a particularly expansive interpretation to physician liability when the outcome is adverse in any way [30]. It also reflects a tactic by plaintiffs' attorneys who can use the threat of criminal sanctions to compel the payment of money damages. This attitude may be increased by the fact that in Italy there are no restrictions on contingent lawyers' fees as in common law countries [53], even if these restrictions are often circumvented and useless [51].

Available evidence shows that Italian physicians have responded to the increase in medical malpractice litigation by resorting to additional diagnostic tests and therapeutic interventions as a defensive mechanism, thereby driving up costs [49]. One rationale is that additional medical testing can help demonstrate physician diligence, prudence, and skill, in case of future litigation. Another side effect of the increased risk of litigation is the reluctance of physicians to offer simple treatments and uncomplicated interventions that may be of value to the patient, but may increase malpractice exposure for the doctor disproportionately.

The practice of defensive medicine is of concern in Italy [12, 17, 66], but it is also an issue in common law countries [51]. In a mail survey among 824 U.S. physicians, 93% reported practicing defensive medicine due to the threat of malpractice liability [75], and the consequence of this attitude has lead to use 5% to 9% of the annual U.S. healthcare budget for defensive medicine [5].

Establishing a financial burden of defensive medicine on the Italian healthcare budget is not possible because there are too few studies analyzing the malpractice phenomenon, for example researching the reasons of adverse events leading to claims or evaluating the social impact of collateral phenomenon of malpractice, such as defensive medicine or rising insurance premiums.

In the only review performed in Italy on cases filed against specialists in orthopaedics and traumatology [18], the primary cause of complaint was alleged wrong execution of the surgery (51% of the cases), followed by inadequate followup (16%), and misdiagnosis (14%).

Otherwise, a retrospective analysis made of 50 legal suits, filed against physicians of different disciplines in the Veneto region (North Italy), revealed problems in regard not only to the methods, appropriateness, and timeliness of medical care but also the organization of the healthcare staff [23].

In a similar study performed on 37 legal suits filed in the Puglia region (South Italy) between 1991 and 2000, the authors reached the same conclusions, and underlined the importance of problems related to the organization of the healthcare staff, equipment, and overall organization of both public and private health facilities of the region [15]. In the same Italian region, on 364 autopsies in which medical malpractice was alleged and for which criminal or civil proceedings had been started, in 70% of the cases the autopsy confirmed that care was appropriate or that medical error did not contribute to death [14].

Similar studies should be mandatory on a national basis, and particularly in the orthopaedic field. With this intention, the Italian Orthopaedic Association has proposed a multicenter retrospective study to identify the frequency of procedures that may be classified as especially complex in order to give a reasoned official opinion on the real difficulty of some surgical procedures [56].

Nevertheless, the major limit of this review and of all the studies investigating the medical malpractice phenomenon in Italy is that there is no official, complete, and current system of monitoring and detection in Italy, which would make it possible to assess clearly the magnitude and character of medical malpractice. Most of the medical malpractice claims information available on a national basis derives from the report published yearly by the National Association of Insurance Carriers (ANIA), with all the limitations related. In July 2007 the Italian Chamber of Deputies ruled a special Parliamentary Commission to inquire into the medical malpractice phenomenon in Italy, but the results are still unknown [25].

Italian politics is particularly attentive to the problem of liability of physicians and healthcare facilities because in Italy the public healthcare system is predominant. In 2005, 76% of health spending was funded by public sources (45.1% in U.S. in the same year) [65]. Very few Italians have a private medical insurance since the governmental medical service (*Servizio Sanitario Nazionale*) was introduced in 1978, which encompasses all citizens. All medical services are available free of charge for all Italian citizens (registered at the governmental medical service), on the basic principle that health should be the fundamental right

of everyone, thus the Italian State is the major party involved in medical malpractice claims. The liability of public or private physicians and of public or private facilities is the same, and medical malpractice is not handled differently based on insurance status of the patients.

In order to allocate liability to public healthcare, it is only required that the act or omission is attributable to an activity of one of its physicians or other employees [39], then both the physician (or the employee) and the public hospital are liable to the damaged patient, according to contractual liability [36]. On the other hand, the private hospital is liable under contractual liability for the damage caused in its structure by a physician, even when the latter is not officially part of its medical staff [37].

The undesirable increase in litigation in Italy over the past two decades will not reverse spontaneously. What is needed to restore balance in the system is a thorough discussion intended to describe the difference between professional diligence and ordinary diligence, between negligence and gross negligence, and between obligation of means and obligation of results. As it stands, the crisis in malpractice has resulted in a crisis in physician-patient relationships in Italy wherein the practice of bureaucratized healthcare has substituted for the essential qualities of the traditional and highly personal role of the physician [4].

A crisis of the physician-patient relationship is regarded as the cause of most litigation [2, 23] and physicians are for their part considered responsible, increasingly more technical operators within super-specialities (shoulder surgery, spinal surgery, etc), and less inclined to a human approach with the patient, even before any medical procedure [2, 52].

In addition to the specific contractual and ethical responsibilities of doctors, there is an obligation to report incidents [7, 67] to reduce the problem of malpractice in Italy as in other countries [24, 78]. Such incidents include both adverse events and near miss, and they are for example errors in blood transfusions or drugs prescription, errors in patient identification, and complications of surgery such as nerve lesions. The Italian Ministry of Health published a manual for all healthcare employees on the "safety of patients and management of clinical risk" to formulate concrete proposals, which together constitute a sort of Decalogue of safety and risk management to be followed in clinical practice [46].

The effectiveness of these measures remains in some doubt [69], and there is growing awareness that traditional legal system reform measures will not solve the problem of high and rising medical liability costs [48, 77]. There is also increasing recognition in the medical community, and even through politicians [6], that such measures do little or nothing to make care safer.

A proposed solution is to reform the professional liability system, introducing a no-fault compensation system [22] already active in Scandinavian countries and in New Zealand [74]. Sweden was the first to introduce this system in 1975, when a Patient Insurance Fund was established and funded by county tax and private practice physicians, dentists, and physiotherapists. Patients who believe they have been injured as a result of medical care in Sweden are encouraged to apply for compensation using forms available in all clinics and hospitals [73, 74]. Once a claim is made, the treating physician prepares a report about the injury, an adjuster establishes the eligibility and then forwards the case for final decision to the specialists who are councilors of the court. Finally, the judges investigate whether there is a chain of causality between injury and treatment, the treatment was medically justified, and the outcome was unavoidable. The claimant receives compensation when a chain of causality between treatment and damage is found, the treatment was not justified and the outcome was avoidable. However, concerns related to the possible application of the Swedish system in other countries with different legal environments have been raised, and the attempt to adopt it even only in part would probably encounter a number of problems [1].

An easier and less burdensome solution for all parties could be represented by "conciliation" (an extrajudicial litigations resolution) [23]. In Italy there is the *commissione conciliativa* (arbitration board) on matters of medical liability established by the Autonomous Province of Bolzano (North Italy). These arbitration boards are voluntary, free, and nonbinding. Their composition explicitly provides for the presence and intervention of one or more forensic physicians, as well as clinical experts. They are based on German experience. In Germany, in the 1970s, the Gutachterkommissionen (advisory committees) and the Schlichtungsstellen (arbitration boards, expert panels for extrajudicial malpractice claims resolution) were established [71]. These collegial bodies are designed to encourage a rapid extrajudicial conciliation of malpractice claims. The Gutachterkommissionen evaluates physician conduct, helping the patient and physician to understand when the claim is, respectively, founded or unfounded, while the Schlichtungsstellen, in case of proven physician liability, concludes the proceedings with a proposal made directly to the insurer, which itself take part on the activity of the Schlichtungsstellen. Even if on a voluntary basis, the number of cases submitted to these panels has been constantly growing since. In 90% of cases decided upon by the panel, civil litigation was avoided [64]. Between 2000 and 2003, the Norddeutsche Schlichtungsstelle, the largest of the 12 institutions active in Germany, concluded 10,513 Schlichtungsverfahren (panel proceedings), more than ¾ of them

related to surgical specialties; most of the claims addressed operations and postoperative therapy. Decisions in favor of the patient were given in 25% to 30% of all the cases [63].

This extrajudicial litigations resolution system seems effective, and should be easily introduced into other countries irrespective of their legal system (common or civil law). Nevertheless, the satisfaction expressed by German patients to their own healthcare service is not entirely positive [70], regardless of the efficiency of the litigation resolution system. Otherwise, the perception of the efficiency of the health system among citizens is sometimes influenced by the media, which stresses the bad more than the good in every case. The Italian media, even as it reports almost daily on "Malasanità" ("bad healthcare"), has also begun to recognize that the concept of a citizen's fundamental right to healthcare from the state and unrealistic patient expectations perception have both contributed to increased malpractice litigation and driven up costs. The legal system has contributed to this phenomenon as well, by redefining the concept of guilt and the informed consent process; the current model is that of the informed consent serving as a contractual framework between the doctor and the patient [59]. Just as suggested by U.S. authors [62], Italian physicians must carefully document the course of medical treatment and patient discussions since these may be vital defenses in a malpractice claim.

In particular the physician, because he or she has the burden of proof that the intervention is complex or unusual, should carefully record the surgical procedure. The drafting of the description of the surgery must respond to the need of an official document, with a value of legal proof. The sequence of surgical activities should be described with formal precision and clarity of exhibition, thereby avoiding dubious or misleading interpretations [57]. This carefulness in providing documentation of data is important also in case of nonoperative procedures, as a preventive measure, so that the patient is involved in the decision-making regarding treatment [20].

Ultimately, the system must have a set of rules that are practical and fair in their application, and are legislatively developed to address adverse outcomes from surgery. As in the United States, using the framework of fact-sensitive case law to determine damages and prescribe standards for medical malpractice on the basis of case law leads to confusing results, defensive physicians, and increased costs. The medical malpractice crisis in Italy will thus continue until legislative bodies decide to address this issue definitively. In the United States when legislative reforms have been introduced, some benefits at least on the supply of physician services were shown [50].

In conclusion, the Italian medical liability system, based on a civil law system, has been described (with some simplifications necessary for the understanding of an international readership not familiar with the Italian judicial system), in order to make a comparison with other international systems. The rising costs of healthcare and insurance premiums, due to the increased medical malpractice litigations that affect Italy, seems similar in other countries that have developed their legislative body on a common-law system. A possible alternative could be extrajudicial litigation resolutions, which otherwise encompasses a mandatory reform of the judicial system on matters of medical malpractice litigations.

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